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AdvaMed
Advanced Medical Technology Association

September 18, 2002

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 01P-0120: Medical Devices; Needle-Bearing Devices; Request for Comments and Information

Dear Madam/Sir:

The Advanced Medical Technology Association (AdvaMed) appreciates this opportunity to respond to the U.S. Food and Drug Administration's (FDA) request for comment and information to assist the agency in determining whether additional FDA actions are necessary to protect healthcare workers from needlestick injuries from medical devices.

AdvaMed represents more than 1100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of the $159 billion of those purchased around the world annually.

AdvaMed and its members are committed to enhancing the safety of healthcare workers, and we encourage the safe and appropriate use of safety products whenever blood and other potentially infectious materials are in use. For a variety of reasons, however, AdvaMed does not support the petition submitted by the Public Citizen's Health Research Group (HRG) and the Service Employees International Union to ban certain devices identified in the petition, develop a mandatory standard to address the risk of needlestick injuries, and require new labeling for conventional syringes.

Specific Comments:

Existing requirements provide sufficient controls.
The existing requirements in the Needlestick Safety and Prevention Act and 29 CFR Part

1910, *Occupational Exposure to Bloodborne Pathogen; Needlesticks and Other Sharps Injuries* provide sufficient controls to minimize the risk of occupational exposure to bloodborne pathogens from contaminated sharps. Employers are required under these provisions to provide a device with engineered safety features unless such a device is unavailable, the safety of the patient or employee is compromised, or the item is not as safe as what is available on the market. To mandate the use of needleless systems or recessed needles in all intravenous (IV) infusion applications by banning alternatives ignores the important role of healthcare professionals to select the product most appropriate for the clinical situation.

In addition, the potential hazards associated with using these devices are well known, and many guidance and other documents, as cited by FDA in its *Federal Register* notice (67 Fed. Reg., 41890-41892, June 20, 2002), have been published to address this issue. AdvaMed believes that there is adequate information available to the health care provider to minimize the risk of using these types of devices; yet no compelling reason for FDA to ban these devices.

In order for FDA to ban a device, it must present an unreasonable and substantial risk of illness or injury. The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (effective April 18, 2001) with its requirements for engineering controls, work procedures, training and other health care worker protections, establishes the necessary controls to reduce the risk of needlestick injury and illness. With such controls in place, there is no basis for FDA to ban medical devices without needlestick prevention features.

The petition's requested ban could increase healthcare costs inappropriately.
Because devices with sharps injury protection features may be more costly than those without such features, healthcare expenses may increase through use of safety devices in applications where they may not be appropriate. For example, needles are typically used to access IV solution containers for the preparation of admixtures. In this application, a sterile needle is used to transfer a drug or solution into an IV infusion container without any patient contact, thereby posing no risk of bloodborne pathogen contamination through needle access. If, as the petition requests, FDA were to ban "IV infusion equipment that does not use needleless technology or recessed needles," protected needles could be mandated for use in circumstances where no public health benefit is realized but costs would rise significantly.

The petition's requested ban could adversely impact patient care.
Healthcare institutions are increasing their use of safety devices and are converting to them in a manner that allows for training of staff and evaluation of the impact on existing systems. This process should be allowed to move forward without the imposition of an FDA mandate to do so. In contrast, banning certain products, as the petition requests, could adversely impact patient care through a reduction in the supply of IV infusion products. Manufacturers may not be able to meet the increased demand for safety devices or there may not be a safety alternative for the previously marketed product.

Healthcare professionals are trained in the use of IV catheters, blood collection devices, and blood collection needle sets, including glass capillary tubing and IV infusion equipment that do not use needle-less technology or recessed needles. There are instances where the use of these devices is beneficial to the donor or patient; e.g., the use of a butterfly is often less painful for the donor and easier to use by the health care provider. Adding a needle guard or other protective device would negate the advantages of the butterfly, making it more cumbersome to use, and thereby increasing the risk of an incomplete sample or hematoma.

Additionally, acceptable alternatives to requested banned products may not always be available. For example, when considering the use of glass capillary tubes, there may not always be a safer alternative. Where possible, plastic or coated tubes could be used to minimize risk of injury, but these would need to be validated for use with each different assay. The OSHA Needlestick Safety and Prevention Act of 2002 already requires such an assessment by each facility. A complete ban of these devices without a thorough assessment and validation of available alternatives could result in the removal of critical tests from the market.

Finally, the requested ban could adversely affect diabetic patients' ability to self-monitor their disease. Today, consumers have many choices regarding lancet devices, and they typically choose those that provide adequate samples with the least amount of pain. The lancet devices are "customizable" for each patient, allowing variable penetration settings most appropriate for each patient. Safe-needle technology has not kept pace with these customizable devices that, if banned, would severely impact patients' ability to self-monitor their diabetes. Moreover, because the cost of developing safe, customizable devices could make them cost-prohibitive for many consumers, FDA (should it pursue a mandate for safer lancet devices in the home) should work closely with the Centers for Medicare & Medicaid Services (CMS) to increase self-testing reimbursement rates.

RECOMMENDATIONS:

AdvaMed makes the following recommendations to help enhance the safety of healthcare workers through safe and appropriate use of safety products whenever blood and other potentially infectious materials are in use:

1. **AdvaMed encourages the development of cost-effective safety products and encourages the safe and appropriate use of safety products whenever blood and other potentially infectious materials are in use.**

   Industry continues to develop safety products, and AdvaMed encourages healthcare professionals to use these products whenever available, for example, valve technology that replaces conventional injection sites on IV tubing sets eliminates the use of needles,

forcing compliance to OSHA standards; also, it provides unlimited access in a cost-effective manner.

2. **Better enforcement of existing legislation, specifically OSHA's Needlestick Safety and Prevention Act of 2002, would reduce the risk of needlestick injuries since it requires facilities to use safety needle devices whenever possible.**

OSHA's Act requires facilities to maintain a sharps injury log. Proper utilization of this log should enable facilities to determine problem areas where improvement in training or procedures is needed. All accrediting agencies need to ensure that this review and training is being done. Documentation of review of the injury log, followed by appropriate training of employees, should be audited. College of American Pathologists (CAP), CLIA (Clinical Laboratory Improvement Amendments), state surveyors, and other auditors need to ensure that the existing law is enforced.

3. **AdvaMed agrees with FDA's position that no additional labeling is required in the use of conventional syringes to provide reasonable assurance of safety and effectiveness.**

FDA is correct in citing 21 CFR 810.109(c) in that the use and precaution required for medical sharps are well known to health care providers, and a warning statement, as proposed by HRG, is not ordinarily required.

4. **Worker injuries could be reduced through proper training of employees.**

A robust educational campaign would likely be far more effective in reducing worker injuries than new labeling, as requested in the petition submitted to FDA. Facilities are required by the Joint Committee on Accreditation of Healthcare Organizations (JCAHO), CAP and other accrediting agencies to provide adequate training to all employees, including proper handling and disposal of sharps. Documentation of training is required. JCAHO joins with OSHA in requiring compliance to the 2000 Act, and includes auditing of compliance in their Assessment Surveys.

Professional organizations should also be encouraged to launch educational campaigns to remind health care workers of their responsibilities regarding sharps.

5. **The best way to approach sharps safety is through a voluntary consensus standard that incorporates expertise from FDA, manufacturers and users.**

This approach has worked well in the past for a variety of medical devices, such as endoscopes and hemodialysis devices, and there is no reason to believe it would not be the appropriate method to develop a performance or safety standard for medical sharps.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Tess Cammack
Associate Vice President
Technology & Regulatory Affairs